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Attorney Docket No.: 18242-508 CIP2 (VI-8 CIP2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Chapman, et al.

SERIAL NUMBER: 10/055,143 EXAMINER: Not Yet Assigned

FILING DATE: January 22, 2002 ART UNIT: 1644

FOR: Method for Purifying a Biological Composition

BOX IDS
Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are enclosed. This Supplemental Information Disclosure Statement is been filed before the mailing date of a first Office Action on the merits in the above identified case. Accordingly, no fee or certification is believed required. However, please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 Reference No. 18242-508 CIP2 (VI-8 CIP2).

Respectfully submitted,

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TRA 1731003v1

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1644

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Attorney Docket No.: 18242-508 CIP2 (VI-8 CIP2) #4

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TRANSMITTAL LETTER

Transmitted herewith for filing in the above-referenced patent application are the following documents:

1. Supplemental Information Disclosure Statement (1 page);
2. Modified Form 1449/PTO (3 pages), in duplicate;
3. Copies of cited references A10-A33, B9-B21, C22-C50; and
4. Return postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617-542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 18242-508 CIP2 (VI-8 CIP2). A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

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TRA 1731000v1

TRA 1653337v1

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PTO/SB (12-97)
Approved for use through 9/30/00. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Modified Form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Numb r	10/055,143
Filing Date	01/22/2002
First Named Inventor	Chapman
Group Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	18242-508 CIP2 (VI-8 CIP2)

U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A10	3,636,196	1/18/72	Bauer, et al.			
	A11	4,429,045	1/31/84	Bass, et al.			5/10/82
	A12	4,567,042	1/28/86	Acree, et al.			6/7/84
	A13	5,229,012	7/20/93	Pall, et al.			6/24/91
	A14	5,547,576	8/20/96	Onishi, et al.			6/6/93
	A15	5,808,011	9/15/98	Gawryl, et al.			7/1/96
	A16	6,093,564	7/25/00	Budowsky, et al.			1/12/98
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	A19	6,114,108	9/5/02	Budowsky			8/29/95
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	A21	6,150,109	11/21/00	Edson, et al.			1/25/99
	A22	5,891,705	4/6/99	Budowsky, et al.			4/8/97
	A23	6,352,695	5/5/02	Budowsky, et al.			10/3/97
	A24	6,166,187	12/26/00	Prusiner, et al.			5/5/99
	A25	6,197,207	3/6/01	Chapman, et al.			5/21/97
	A26	6,221,614	4/24/01	Prusiner, et al.			1/20/99
	A27	6,251,295	6/26/01	Johnson			1/8/98
	A28	6,369,048	4/9/02	Budowsky, et al.			1/12/98
	A29	6,403,359	1/11/02	Purmal, et al.			9/25/98
	A30	6,410,219	6/25/02	Cook, et al.			3/30/00

U.S. PUBLISHED APPLICATION DOCUMENTS

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A31	2002/0034724	3/21/02	Edson, et al.			6/8/01
	A32	2001/0009756	7/26/01	Hei, et al.			7/8/98
	A33	2001/0018179	12/30/01	Hei			7/8/98

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	No
	B9	WO	97/07674	Pentose Pharmaceuticals, Inc.	3/6/97		
	B10	WO	98/30327	CERUS Corporation	7/16/98		
	B11	WO	98/45415	Pentose Pharmaceuticals, Inc.	10/15/98		
	B12	WO	99/17802	Pentose Pharmaceuticals, Inc.	4/15/99		
	B13	WO	99/34797	Pentose Pharmaceuticals, Inc.	7/15/99		
	B14	WO	99/34914	Cerus Corporation	7/15/99		
	B15	WO	99/34915	Cerus Corporation	7/15/99		
	B16	WO	00/43048	Common Services Agency	7/21/00		
	B17	WO	00/43782	The Regents of The University of California	7/27/00		
	B18	WO	99/34839	Cerus Corporation	7/15/99		
	B19	WO	00/18412	Pentose Pharmaceuticals, Inc.	4/6/00		
	B20	WO	00/43549	V.I. Technologies, Inc.	7/27/00		
	B21	WO	00/74731	Baxter International, Inc.	12/14/00		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C22	Mollison et al. (1997). "Blood Transfusion in Clinical Medicine" *Tenth Edition, Blackwell Science*: 4.
	C23	Brown, et al. (1998). "The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy" *Transfusion* 38: 810-816.
	C24	Ackerman, et al. (1998). **Abstract:** "INACTINE™ - A potent and Selective Method for Inactivating Viruses in Contaminated Blood Products" *25th Congress of the International Society of Blood Transfusions (ISBT)*.
	C25	Edson, et al. (1998). **Abstract:** "INACTINE™ - An Inactivation Technology for Reducing the Viral Infectivity of Plasma-Derived Proteins and Red Blood Cells" *IBC 2nd International Symposium on Viral Clearance.*
	C26	Edson, et al. (1998) **Abstract S277:** "INACTINE™ - A Viral Inactivation Technology for Reducing the Infectivity of Plasma-Derived Proteins" *51st Annual Meeting of the American Association of Blood Banks (AABB), held in Philadelphia, PA, October 31 – November 4, 1998.*
	C27	Purmal, et al. (1998). **Abstract S279:** "INACTINE™ - A Method for Viral Inactivation in Red Blood Cell Concentrate" *51st Annual Meeting of the American Association of Blood Banks (AABB), held in Philadelphia, PA, 1998; Oct. 31 – Nov. 4, 1998*.
	C28	Ackerman, et al. (1999). **Abstract:** "INACTINE™ - A Viral Inactivation Technology for Reducing the Infectivity of Plasma-Derived Proteins" *CHI 5th Annual Conference on Blood Safety & Screening, held in McLean, VA, Feb. 22-24, 1999.*
	C29	Edson, et al. (1999). **Abstract S496-040C:** "Viral Inactivation in Red Blood Cell Concentrates by INACTINE™: Mechanism of Action and Lack of Effort on Red Cell Physiology" *52nd Annual Meeting of the American Association of Blood Banks (AABB).*
	C30	Edson, et al. (1999). **Abstract S85-P:** "Evaluation of INACTINE™ as a Second Virucidal Step for Solvent Detergent Treated Plasma for Transfusion" *52nd Annual Meeting of the American Association of Blood Banks (AABB).*
	C31	Lazo, et al. (2000). **Abstract S141-0401:** "Viral Inactivation of U1 Cell-Associated HIV in Red Blood Cell Concentrates Treated by the INACTINE™ Technology:" *53rd Annual Meeting of the American Association of Blood Banks (AABB), held in Washington, DC, November 4-8, 2000.*
	C32	Purmal, et al.(2000) **Abstract**: "Pathogen Inactivated Red Blood Cells Prepared with the INACTINE™ Technology: Effect on Red Cell Physiology and Bacterial Growth" along with associated poster. *53rd Annual Meeting of the American Association of Blood Banks (AABB), held in Washington, DC, November 4-8, 2000.*
	C33	Chapman, J. et al. (2000). **Abstract No. 257:** "Preclinical Safety Assessment of Red Blood Cells Virally Inactivated by INACTINE™: Lack of Neoantigenicity", along with the associated poster. *American Society of Hematology, 42nd Annual Meeting, held in san Francisco, CA, 12/1 - 12/5/00.*
	C34	Pereira, M. et al. (2001). **Abstract SP175:** "Inactivation of Virulent Tryoanasoma Cruzi Trypomastigotes by the INACTINE™ Process"; along with the associated poster *54th Annual AABB Meeting, San Antonio, TX, October 13-17, 2001.*
	C35	AuBuchon, J.P. et al. (2001). **Abstract S136-040K:** "Phase I Clinical Trial of Pathogen-Inactivated Red Blood Cells Using INACTINE™ Chemistry" *54th Annual AABB Meeting, San Antonio, TX, October 13-17, 2001.*

OTHER PRIOR ART – NON-PATENT LITERATURE DOCUMENTS		
Exam Initials	**Cite No.**	**Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.**
	C36	Purmal, A. et al. (2001). **Abstract SP185:** "Removal of White Blood Cell and Plasma Proteins from Leukofiltered Red Blood Cell Concentrates by INACTINE™ Pathogen Inactivation", along with the associated poster, *54th Annual AABB Meeting, San Antonio, TX, October 13-17, 2001.*
	C37	Chapman, J. et al. (2001). **Abstract SP181:** "Lack of Toxicity of PEN110 Treated Red Blood Cells Without PEN110 Removal in New Zealand White Rabbits", along with the associated poster *54th Annual AABB Meeting, San Antonio, TX, October 13-17, 2001.*
	C38	Purmal, et al. (2001). **Abstract SP183:** "Collection System Equivalency Using the INACTINE™ Process for Pathogen Inactivation: Red Cell Quality assessment" along with the associated poster *54th Annual AABB Meeting, San Antonio, TX, October 13-17, 2001.*
	C39	Zavizion, et al. (2001). **Abstract SP180:**:"Collection System Equivalency Using the INACTINE™ Process for Pathogen Inactivation: Bacterial Inactivation Assessment" along with the associated poster *54th Annual AABB Meeting, San Antonio, TX, October 13-17, 2001.*
	C40	43rd Annual ASH Meeting, held in Orlando, FL, December 7-11, 2001: **Abstract 2268:** "High Efficiency Removal of Prion Proteins from Red Cell Concentrates by the INACTINE™ Process", along with the associated poster.
	C41	Popovsky, M.A. (2001). "Frozen and Washed Red Blood Cells: New Approaches and Applications" *Transfusion and Apheresis Science* 25:193-194.
	C42	Valeri, C.R. et al. (1984). "The 24-Hour Posttransfusion Survival, Oxygen Transport Function, and Residual Hemolysis of Human Outdated-Rejuvenated Red Cell Concentrates After Washing and Storage at 4°C for 24 to 72 Hours" *Transfusion* 24(4): 323-26.
	C43	Valeri, C.R. et al. (1980). "Viability and Function of Outdated Human Red Blood Cells After Biochemical Modification to Improve Oxygen Transport Function, Freezing, Thawing, Washing, Postthaw Storage at 4°C, Perfusion *In Vitro* Through a Bubble Oxygenator, and Autotransfusion" *Transfusion* 20(1): 39-46.
	C44	DeVenuto, F. et al. (1974). "Rejuvenation of Human Red Blood Cells During Liquid Storage" *Transfusion* 14(4): 338-344.
	C45	Valeri C. R. et al. (1980). "Therapeutic Effectiveness and Safety of Outdated Human Red Blood Cells Rejuvenated to Restore Oxygen Transport Function to Normal, Frozen for 3 to 4 Years at -80° C, Washed, and Stored at 4°C for 24 Hours Prior to Rapid Infusion" *Transfusion* 20(2):159-170.
	C46	Valeri, C.R. et al. (1980). "Therapeutic Effectiveness and Safety of Outdated Human Red Blood Cells Rejuvenated to Improve Oxygen Transport Function, Frozen for About 1.5 Years at 80° C, Washed, and Stored at 4° C for About 24 Hours Prior to Rapid Infusion" *Transfusion* 20 (3): 263-276.
	C47	Tsvetkova, E.A et al. (2001). "Principles of Selective Inactivation of a Viral Genome. Comparative Kinetic Study of Modification of the Viral RNA and Model Protein with Oligoaziridines" Biochemistry (Moscow) 66(8): 875-884. Translated from Biokhimiya 66 (8) 2001:1078-1088.
	C48	Brown, et al. (1998). "A Universal Inactivant for Decontaminating Blood and Biopharmaceutical Products" *Biologicals* 26: 39-47.
	C49	Burrage, et al. (1999). "Inactivation of Viruses by Aziridines" Brown F, Vyas G (eds). *Advances in Transfusion Saftey. Dev Biol. Basel, Karger* 102: 131-139.
	C50	Yamamoto, Nobuto (1966). "Mechanism of Inactivation of DNA and RNA Bacteriophages by Alkylating Agents In Vitro" *Cancer Research* 26 (part 1): 2301-2306.

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.